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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/890,688	KATO ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-9* is/are pending in the application.

4a) Of the above claim(s) *1,7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This action is in response to Applicant's response filed on May 28, 2004. Currently, Claims 1-3 and 5-9 are pending, Claims 1, 7 and 9 have been withdrawn, and Claims 2-3, 5, 6 and 8 remain rejected. This action contains a new rejection necessitated by Applicants' amendment. This action is FINAL.

Applicants' arguments have been considered, but are not persuasive for the reasons below. Any objections or rejections not reiterated below have been withdrawn. Specifically, the 112, 1st paragraph written description rejection has been withdrawn in view of Applicants' amendments. Furthermore, the objection to the claims (¶ 7 from the last office action) and the description of the drawings (¶ 8 from the last office action) has been withdrawn in view of Applicants' amendments.

THE FOLLOWING IS A NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS

2. Claim 2 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter, a product of nature. Claim 2 is directed to a nucleic acid sequence encoding the protein of SEQ ID NO: 2, which is a nucleic acid sequence that occurs in nature (e.g., chromosomal DNA in any human cell). Thus, the claim reads on a chromosome *per se*, which is a product of nature and is not patentable. To overcome this rejection it is suggested that applicant use the language --isolated-- or --purified-- in connection with the nucleic acid sequence to identify a product that is not found in nature. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C. 101. See MPEP 2105.

MAINTAINED OBJECTIONS AND REJECTIONS

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

While Applicants have amended the title to recite, "NUCLEOTIDE SEQUENCE ENCODING A HUMAN PROTEIN," this title is not descriptive, as it does not describe the human protein. Accordingly, because the amended title does not clearly indicate the invention to which the claims are directed, the objection is maintained.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 2-3, 5, 6 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

I. *The specification does not assert a specific utility because the utilities asserted by Applicants are general utilities that would be applicable to broad class of the invention.*

MPEP 2107.01 states:

> A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.
>
> Applicants alleged the following utilities:

- The protein provided by this application is useful for detecting the corresponding receptor or ligand as an intracellular targeting protein, for screening novel small molecule medicinals and so on, since each protein is considered to function within a cell.
- The protein is useful as an antigen for manufacturing the antibody against the proteins.
- The DNA fragment provided by this application is useful as a probe for gene diagnosis or as a gene source for gene therapy.
- The DNA fragment can be also used as a gene source for mass production of the protein.

(pg. 80, lines 13-21)

These utilities are not considered to be specific utilities for several reasons. First, the specification does not teach any specific receptors, ligands, or antigens that correspond with the protein. Additionally, as stated above, MPEP 2107.01 states "a claim to a polynucleotide whose use is disclosed simply as a gene probe" would not be considered to be specific in the absence of a disclosure of a specific DNA target". In the instant case, no specific DNA target is disclosed. Additionally, the utility of a gene source for gene therapy is not specific because any gene source could potentially be used in gene therapy, and furthermore, the specification has not disclosed any specific disease to be treated by gene therapy using the instant invention. Finally, the assertions that the proteins can be used to make antibodies and that the DNA fragment can be used as a gene source for "mass production" of the protein are not considered to be specific because these utilities are applicable to a general class of compounds, namely proteins and nucleic acids. Accordingly, the claimed invention is not supported by a specific utility.

II. *The specification does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use.*

MPEP 2107.01 states:

> A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities...the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition...

In the instant case, the alleged utilities summarized above do not define a "real world" use because the claimed invention can only be used for "basic research such as studying the properties of the claimed product itself *or the mechanisms in which the material is involved*" or for use in "a method of treating an unspecified disease or condition." (emphasis added) That is, the asserted utility of the claimed invention provides opportunities to detect or treat *unspecified* diseases, detecting unknown receptors, ligands, or for screening for unknown novel small molecule medicinals. At best, these utilities fall into the (A) and (B) categories listed above and require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

In *Brenner v. Manson*, 148 USPQ 696 (US SupCt 1966) the Court hold, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy."

In the instant case, the specification teaches SEQ ID NO: 1 is a *human* cDNA with an open reading frame, and that the protein encoded by SEQ ID NO: 1 (i.e., SEQ ID NO: 2) was

37.2% similar to a *bacterial* GTP-binding protein CgpA (*Caulobacter crescentus*), *except for the N-terminal region*. (emphasis added) (pgs. 20-21).

However, Applicants do not teach what this information is useful for. Applicants' assertion that SEQ ID NO: 2 is 37.2% homologous to a GTP-binding protein from *Caulobacter crescentus* (except for the N-terminal region) does not provide the skilled artisan with any information that would constitute a "real world" use. That is, the skilled artisan would have to prepare, isolate, and analyze the protein to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation on the protein itself would need to be required before it could be used. Accordingly, because one skilled in the art would need to carry out further research to identify or reasonably confirm a "real world" context of use, the claimed invention lacks a substantial utility.

III. *The specification is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics on the invention.*

MPEP 2107 states:

> An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

Neither Applicants, nor the prior art have provided any evidence as to the function of the claimed invention; the utility is not specific or substantial, and it is not apparent as to how "a person of ordinary skill in the art would immediately appreciate why the invention is useful". For these reasons, the specification is not supported by a well-established utility.

Claim Rejections - 35 USC § 112 - Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2-3, 5, 6 and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the specification is not enabling of using SEQ ID NO: 1 for the following reasons. There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (see *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include, but are not limited to:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) ***Nature of the Invention & Breadth of the Claims***

The claims are drawn to a DNA fragment encoding SEQ ID NO: 2, the nucleic acid of SEQ ID NO: 1, vectors and host cells.

Thus, the claims encompass genomic DNA, which includes introns and regulatory sequences (e.g., promoters, enhancers, and any other regulatory elements).

(2) ***Relative Skill of those in the Art, State of the Prior Art, Amount of Direction or Guidance Presented & Presence or Absence of Working Examples***

The specification teaches SEQ ID NO: 1 is human cDNA with an open reading frame (pgs. 15, 20 and 21). The specification also teaches that in the protein encoded by SEQ ID NO: 1 (i.e., SEQ ID NO: 2) "there was found a similarity to bacteria GTP-binding protein CgpA (Accession No. AAC69623)" (pg. 20, lines 29-30). Specifically, the specification teaches in a comparison of SEQ ID NO: 1 and the *bacteria* GTP-binding protein CgpA (in Figure 1), "[o]ver the whole region, *except for the N-terminal region, they had a homology of 37.2%.*" (emphasis added) (pg. 21, lines 5-6). Finally, the specification teaches:

> [A]s result of reference to GenBank on the basis of the base sequence of clone 1 cDNA, those having a homology of not less than 90 % (e.g. Accession No. M429983) were found to have been registered in EST, but as it is of the partial sequence, *it cannot be decided whether or not the same protein as that encoded by clone 1 is encoded.*

(emphasis added) (pg. 21, lines 7-11).

The specification does not teach any examples of using SEQ ID NO: 1, but broadly states that "GTP-binding protein plays an important role in route of the intracellular signal transduction" (pg. 21, lines 12-13). Accordingly, the specification does not provide any guidance or teaching on how to use the claimed nucleic acids, and at best, teaches that "except for the N-terminal region" the claimed *human* cDNA of SEQ ID NO: 1 has a homology of only 37.2% with a *bacterial* GTP-binding protein CgpA.

Several findings with respect to the prior art and state of the art have been made. First, the bacterial GTP-binding protein CgpA (Accession No. AAC69623, from *Caulobacter crescentus*, enclosed herein) was made available on November 1st, 1998, and since then, a search of the art has not found any publications referencing or relating to this Accession Number. In a search for GTP-binding proteins of *Caulobacter crescentus*, the following articles teach the discovery, trial and error process and difficulties encountered by groups working on the GTP-binding protein of the *Caulobacter crescentus* gene (CgtA).

In 1997, Maddock et al. (J of Bacteriology 179(20): 6426-6431) identified the CgtA gene by carrying out significant molecular analysis, including isolation and characterization assays, such as antibody production and immunoblotting, as well as, testing CgtA protein levels during the cell cycle (pgs. 6428-9). Maddock concluded, "CgtA is a minor, yet essential protein found throughout the Caulobacter cell cycle". (pg. 6431, 1st column).

In 1999, Lin et al. (J of Bacteriology 181(18): 5825-5832) further characterized the CgtA protein, using binding assays, and concluded their study "demonstrated that the mechanism of regulation of CgtA is different from that of the well-characterized Ras-like GTP-binding proteins" (pg. 5831, 1st column). Additionally, Lin found "the role of the N-terminal extension is unknown", and "clearly, the challenge ahead is to determine the functional consequences of the CgtA-GTP-to-CgtA-GDP shift during *C. crescentus* growth." (pg. 5831, both columns).

In 2000, Lin et al. (FEBS Letters 484(1): 29-32), demonstrated "that although the N-terminus of CgtA is required for function in vivo, this domain plays no significant role in the guanine nucleotide binding, exchange or GTPas activity" (abstract). Lin also speculates on the N-terminus, questioning, "What might be the cellular role of the N-terminal domain?" and then

concludes, "It will be of interest to see if the N-terminal domain is necessary" for interaction with Rpl113 (see pg. 32, both columns).

In 2001, Lin et al. (Molecular Microbiology 39(4): 924-934) examined the functional consequences of altering amino acid residues within the putative effector-binding domain of CgtA (abstract). Specifically, Lin concluded that a substitution of T193 led to a protein incapable of functioning in vivo (pg. 925, 1st column and pg. 931, 1st column).

Over the four years of literature regarding the GTP-binding protein of the *Caulobacter crescentus* gene (CgtA) (which extends from before the filing to after the filing of the present application), the art has shown considerable amounts of experimentation in trying to determine the function and interaction of CgtA (a bacterial GTP-binding protein of *Caulobacter crescentus*). Specifically, significant questions remain about the N-terminus of CgtA, as well as, CgtA's interaction in cell growth. Additionally, the art has shown that even single amino acid changes can alter the function of CgtA, and therefore, certain critical amino acids required for in vivo function. Therefore, even after 4 years of research from the initial discovery of the GTP-binding protein of CgtA, substantial experimentation is still required.

In the present case, the specification and the art are silent as to any teachings regarding the function of *Caulobacter crescentus* GTP-binding protein CgpA. For example, the specification asserts the DNA fragment that encodes SEQ ID NO: 2 is 37.2% identical to the *Caulobacter crescentus* GTP-binding protein CgpA, not including the N-terminal region. In *Caulobacter crescentus* GTP-binding protein CgtA, the art specifically teaches the N-terminus is required for in vivo function, but has yet to be fully elucidated. However, in the instant case, the homology-based assertions have not taken the N-terminus into account, let alone carried out the

extensive research demonstrated by the prior art to characterize the *Caulobacter crescentus* GTP-binding protein CgtA. Consequently, the state of the art is high, whereas the guidance and direction given in the specification is very low.

(3) ***Quantity of Experimentation Necessary & the Unpredictability of the Art***

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art.

In the instant case, the specification, nor the prior art teaches how to use the claimed nucleic acids, and at best, teaches that "except for the N-terminal region" the claimed *human* cDNA of SEQ ID NO: 1 has a homology of only 37.2% with a *bacterial* GTP-binding protein CgpA. As discussed above, the prior art has shown the N-terminal region is necessary for in vivo function in other *Caulobacter crescentus* GTP-binding proteins, but yet the function of the N-terminal region has not been fully characterized. In the instant case, the specification is silent as to any function of the N-terminal region, nor does the specification specifically define what constitutes the N-terminal region, and finally, the N-terminal region is excluded when performing sequence comparisons. Accordingly, the lack of information regarding the N-terminus of the claimed invention does not teach the skilled artisan how the claimed invention functions and therefore, does not teach the skilled artisan how to use the claimed invention.

In order to carry out making and using of the claimed nucleic acids, the experimentation required by the skilled artisan would be considered undue. The skilled artisan would be required to carry out similar assays and experiments like those performed by groups working on *Caulobacter crescentus* GTP-binding protein CgtA (see above). As demonstrated by these teachings, such experimentation requires a large amount of trial and error analysis resulting in unpredictable outcomes (see above). In the instant case, the specification has provided the skilled artisan with little to no starting point for experimentation purposes. The specification asserts the claimed invention, a *human* cDNA encoding a protein, is minimally homologous to a *bacterial* protein. The prior art is silent as to any teachings regarding this bacterial protein, and the specification does not provide any guidance that would aid the skilled artisan in the function and ultimate use of the claimed invention. In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. However, "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Applicants Arguments

Applicants' argue there is a "well established utility" for the instant invention. Applicants argue:

> The specification in Example 1 on page 20, line 10 to page 21, line 13 discloses the function of the of the claimed invention. Specifically, the CDNA clone 14P02573 encodes a human protein that is a human homologue of the bacterial GTP-binding protein CgpA. As noted at page 21, lines 12-13, GTP-binding proteins play an important role in intracellular signal transduction. Thus, one of skill in the art, upon reading the specification, would reasonably believe that the present invention has the structure and function of a GTP-binding protein CgpA.

See page 6 of Applicants response.

Furthermore, Applicants argue it is well established that bacterial GTP-binding protein CgpA are "essential for cell viability and are present at levels throughout the cell cycle," and therefore, "since the invention is a human homologue of the GTP-binding protein CgpA, it too is essential for cell viability and is present in levels throughout the cell cycle." See page 7 of Applicants response.

Applicants argue the claimed invention can be used for making and using antibodies, nucleic acid probes, and developing and screening for medicinal compounds. Furthermore, that because antibodies and diagnostic reagents are well known and widely used in industry, the invention has a real world use.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, in order to have a "well-established" utility, the utility must be specific and substantial. See MPEP 2107 and the Utility Guidelines (66 Fed. Reg. 1097, 1098). However, the instant invention does not have a specific or substantial utility. See above rejection and discussion below. Furthermore, in order to have a "well-established" utility, the utility must be immediately apparent to one skilled in the art based on the characteristics of the invention. Applicants argue page 21, lines 12-13 provides such a utility. Page 21, lines 12-13 state, "GTP-

binding protein plays an important role in route of the intracellular signal transduction." However, the specification does not state what role the GTP-binding protein plays, only that it is an "important" role in the "route of the intracellular signal transduction." It is not immediately apparent to one skilled in the art how a protein that is "important in the route of the intracellular signal transduction" is useful. Further experimentation is required to determine the role of GTP-binding proteins and a real world use for these proteins.

Applicants conclude that one skilled in the art, upon reading the specification "would reasonably believe that the present invention has the structure and function of a GTP-binding protein CgpA." This conclusion is problematic for several reasons. First, the specification teaches the protein encoded by SEQ ID NO: 1 (i.e., SEQ ID NO: 2) was only 37.2% similar to a bacterial GTP-binding protein CgpA (*Caulobacter crescentus*), *except for the N-terminal region.* (emphasis added) (pgs. 20-21) Thus, the structural similarity is minimal in light of the low percent similarity (37.2%) and the lack of a percent similarity calculation including the N-terminal. Furthermore, as discussed above, the prior art has shown the N-terminal region is necessary for in vivo function in other *Caulobacter crescentus* GTP-binding proteins, but yet the function of the N-terminal region has not been fully characterized. The specification is silent as to any function of the N-terminal region, nor does the specification specifically define what constitutes the N-terminal region, and finally, the N-terminal region is excluded when performing sequence comparisons. Accordingly, the minimal percent similarity and the lack of information regarding the N-terminus of the claimed invention does not teach the skilled artisan how the claimed invention functions and therefore, does not constitute the structure and function of a GTP-binding protein CgpA.

Applicants' argument that the claimed invention has a well-established utility because it is essential for cell viability and is present in levels throughout the cell cycle is not persuasive. First, even assuming the claimed invention essential for cell viability and is present in levels throughout the cell cycle, it is not immediately apparent why this useful in a patent sense (i.e., having a specific and substantial utility). For example, once the skilled artisan knows the claimed invention is "present" in levels throughout the cell cycle; the skilled artisan would have to conduct further research to determine a real world use. Furthermore, even assuming the claimed invention is essential for cell viability (which has not been established for the claimed invention in humans), the function of the gene still needs to be elucidated and a real world use must be found. For example, over the four years of literature regarding the GTP-binding protein of the *Caulobacter crescentus* gene (CgtA), the art has shown considerable amounts of experimentation in trying to determine the function and interaction of CgtA (a bacterial GTP-binding protein of *Caulobacter crescentus*). Specifically, significant questions remain about the N-terminus of CgtA, as well as, CgtA's interaction in cell growth. Additionally, the art has shown that even single amino acid changes can alter the function of CgtA, and therefore, certain critical amino acids required for in vivo function. Therefore, even after 4 years of research from the initial discovery of the GTP-binding protein of CgtA, substantial experimentation is still required. Accordingly, because the function of the instant invention and CgtA is yet to be elucidated, and because substantial experimentation is still required to determine a real world use, the claimed invention lacks utility.

Applicants argument that the claimed invention can be used for making and using antibodies, nucleic acid probes, and in developing and screening for medicinal compounds is not

persuasive because these utilities are not specific or substantial. These asserted utilities are not specific because the specification does not teach any specific receptors, ligands, or antigens that correspond with the protein or any specific DNA targets. Furthermore, these utilities are applicable to a general class of compounds, namely proteins and nucleic acids, and therefore, are not specific. Furthermore, Applicants argument that because antibodies and diagnostic reagents are well known and widely used in industry, the invention has a real world use is also not persuasive because the antibodies and diagnostic uses asserted in the specification are not specific or substantial (see discussion above).

Conclusion

8. No claims are allowable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Alexander H. Spiegler
August 4, 2004

CARLA J. MYERS
PRIMARY EXAMINER